DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

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# WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Grippa, Vice President
B-G Lobster & Shrimp Corp.
95 South Street
New York, NY 10038

July 30, 2001

Ref: NYK-2001-104

Dear Mr. Grippa:

We inspected your fish processing facility, located at the above address, on June 25 and 27, 2001 and found that you have serious deviations from the Seafood HACCP regulations (Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)). These deviations, which were previously brought to your attention, cause your scombrotoxin (histamine) forming species of fish (e.g., tuna, mahi mahi, mackerel, and bluefish) to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at www.fda.gov.

The deviations included, but are not limited to, the following:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for histamine forming fish does not list the critical control points of street display and refrigerated storage for controlling the histamine food safety hazard. Further, for each critical control point (including the receiving critical control point that you do list in your HACCP plan) you must then list the appropriate critical limits to control the histamine hazard; the monitoring procedures to ensure compliance with the critical limits; the corrective actions to be taken in response to deviations from critical limits; the record keeping system that documents the monitoring of critical control points; and the verification procedures to ensure the plan is being effectively implemented.

2. You must implement the monitoring procedures and record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b) and 123.6(c)(7). However, your firm did not follow monitoring procedures and record monitoring observations at the receiving critical control point to control the histamine hazard listed in your HACCP plan for histamine forming species of fish. For example, there was no record that the fresh mahi mahi observed during the first day of the inspection was checked for adequacy of ice or internal temperature upon receipt. Further, there was no record that histamine-forming fish were checked for adequacy of ice during street display and there was no record that the temperature of the storage refrigerator was monitored during the second day of the inspection.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

The above deviations were also noted during prior inspections of your firm. Attempts to correct the deviations have been unsuccessful to date. During the current inspection, it was apparent that neither you nor your employees who routinely handle histamine forming fish were familiar with your firm's HACCP plan and the requirements of the Seafood HACCP regulations. Your letter dated July 27 (postmarked June 29) sent in response to the current inspection does not adequately address the deviations observed. For these reasons, we recommend that you consider hiring a qualified consultant who has successfully completed training in the application of seafood HACCP principles to assist you in preparing and implementing a written HACCP plan. Alternatively, you and/or your employee(s) must complete the HACCP training necessary to enable your firm to comply with the requirements of the seafood HACCP regulations.

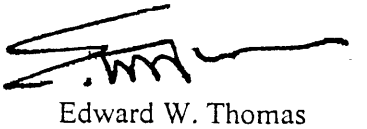
Of course, the FDA cannot recommend or endorse a particular consultant. However, we recommend that you contact the New York Sea Grant Extension Program at (631) 632-8730 for information about seafood HACCP training courses and alternatives.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Form FDA 483) (copy enclosed) issued to and discussed with you at the conclusion of the inspection may not list all the deviations at your seafood processing facility. You are responsible for ensuring that your facility operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,



Edward W. Thomas
Acting District Director

Enclosure: Form FDA 483 dated June 27, 2001